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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Hashem Akhavan-Tafti, Renuka de Silva, Nicole M. Cilli, William C. Cripps, Richard S. Handley, Elizabeth A. O'Connor, Lekkala V. Reddy, and Sarada Siripurapu

Serial No.: 10/714,763 Group Art Unit: 1637

Filed: November 17, 2003 Examiner: S. Mummert

For: METHODS OF USING CLEAVABLE SOLID PHASES FOR ISOLATING NUCLEIC ACIDS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97(b)(3) and 1.98

Sir:

The information statement is being submitted after the issuance of a first Office Action to correct deficiencies pointed out in the Office Action mailed on Dec. 12, 2005. Provided herewith are a listing of references in the attached form PTO-SB/08. Applicants submit the references in the present case pursuant to their obligation under 37 CFR §§ 1.56, 1.97(b)(3) and 1.98. A concise statement of their relevance of each document is as follows.

Reference A ((U.S. Patent 4,699,717) describes ion exchange resins for chromatographic separation of nucleic acids. Resins comprise a carrier such as silanized silica particles with ion exchange materials attached. The materials are used for separating plasmid DNA from cellular lysates by eluting the column with a

gradient of increasing ionic strength.

Reference B (U.S. Patent 5,057,426) describes the separation of long chain nucleic acids on a porous carrier bearing an ion exchange group. The materials are used for separating long chain nucleic acids from shorter nucleic acids and other materials by adsorbing a sample on the carrier and eluting with a solution of high ionic strength.

Reference C (U.S. Patent 4,395,271) discloses methods of making porous magnetic glass particles, comprising superparamagnetic iron oxide enclosed in controlled pore glass.

Reference D (U.S. Patent 4,233,169) discloses porous magnetic glass particles, comprising superparamagnetic iron oxide enclosed in controlled pore glass.

Reference E (U.S. Patent 4,297,337) discloses the use of porous magnetic glass particles, comprising superparamagnetic iron oxide enclosed in controlled pore glass, in immunoassays

Reference F (U.S. Patent 4,554,088) discloses paramagnetic particles comprising a metal oxide core surrounded by a coat of polymeric silane coupled to a bioaffinity adsorbent, especially antibodies, enzymes and binding proteins.

Reference G (U.S. Patent 5,356,713) discloses a magnetizable microsphere comprised of a core of magnetizable particles surrounded by a shell of a hydrophobic vinylaromatic monomer.The particles are alleged to be useful for immobilizing biologically active substances such as proteins, antigens and medicinal products.

Reference H (U.S. Patent 5,395,688) discloses fluorescent particles having a polymer core coated with a mixed paramagnetic metal oxide-polymer layer. The particle surface can be coated further with a functionalized polymer for coupling of biological material such as antigens, antibodies, enzymes or DNA/RNA hybridization and used as solid phase for various types of immunoassays, DNA/RNA hybridization probes assays, affinity purification, and cell separation.

Reference I (U.S. Patent 4,774,265) discloses paramagnetic particles comprising a polymer core to which is adsorbed metal oxide. Use in unspecified medical or diagnostic purposes is alleged but not exemplified.

Reference J (U.S. Patent 5,091,206) discloses magnetic particles comprising a polymeric core particle coated with a paramagnetic metal oxide particle-polymer layer. The particle surface can be coated further with a functional groups such as carboxyl, amino, hydroxyl sulfonic acid and aldehydes for coupling of biological material such as antigens, antibodies, enzymes or DNA/RNA hybridization and used as solid phase for various types of immunoassays, DNA/RNA hybridization probes assays, affinity purification, and cell separation.

Reference K (U.S. Patent 5,866,099) discloses the preparation of magnetic particles by coprecipitation of mixtures of two metal salts in the presence of a protein or polymer to coordinate the metal salt and entrap the mixed metal oxide particle. The particles are stated to be useful in biological and medical fields

including sell capture, as a contrast agent in NMR imaging, immobilized enzyme reactions, and immunoassays.

Reference L (U.S. Patent 6,291,166) discloses bare alumina particles for irreversible capture of DNA and RNA. The immobilized particles are useful for archiving and nucleic acid hybridization methods including amplification.

Reference M (U.S. Patent 4,628,037) discloses magnetically responsive particles prepared by silanization of a metal oxide core. The particles can be covalently coupled to bioaffinity molecules for use in specific binding reactions.

Reference N (U.S. Patent 4,627,040) discloses magnetically responsive particles prepared by silanization of a metal oxide core. The particles can be covalently coupled to bioaffinity molecules, including nucleic acids, for use in specific binding reactions.

Reference O (U.S. Patent 4,695,393) discloses a process for preparing paramagnetic particles comprising a metal oxide core surrounded by a coat of polymeric silane coupled to a bioaffinity adsorbent, especially antibodies, enzymes and binding proteins.

Reference P (U.S. Patent 4,698,302), div. of 4,554,088 Ref. F discloses paramagnetic particles comprising a metal oxide core surrounded by a coat of polymeric silane coupled to an enzyme for performing an enzymatic reaction.

Reference Q (U.S. Patent 4,654,267) discloses paramagnetic particles comprising a polymer core to which is adsorbed metal oxide. Use in unspecified medical or diagnostic purposes is

alleged but not exemplified.

Reference R (U.S. Patent 5,411,730) discloses magnetic particles can also be formed by precipitating metal oxide particles in the presence of the oligosaccharide dextran and optional phospholipid additional coating. The particles are described as being used for hyperthermia techniques, localized heating techniques, as a contrast agent in NMR imaging, and tissue specific delivery of therapeutic agents.

Reference S (U.S. Patent 5,707,559) discloses spiroadamantyl-stabilized dioxetanes which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference T (Eur. Patent 0496822B1, in German) discloses chromatographic support materials comprising a porous particulate material linked to terminal 1°, 2°, or 3° amine groups for use chromatographically separating nucleic acids. Samples are eluted with a mobile phase containing a buffer, urea, and a gradient of salt concentration.

Reference U (Eur. Appl. 1243649A1) describes polymeric resin particles for isolation and purification of nucleic acids. Carboxylate-modified linear non-crosslinked polymeric particles polymers having quaternary ammonium head groups are disclosed. The linear polymers incorporate quaternary tetraalkylammonium groups. The alkyl groups are specified as methyl or ethyl groups.

Reference V (Eur. Patent EP01036082) describes a method of extracting a nucleic acid from a sample using the materials as

described in related U.S. Patent 6,914,137 (Reference XX, below).

Reference W (PCT WO03/053934) discloses ketene dithioacetals undergo oxidative cleavage by enzymatic oxidation with a peroxidase enzyme and hydrogen peroxide to produce chemiluminescence for purposes of detecting peroxidase enzymes or peroxidase-linked specific binding partners in assays.

Reference X (U.S. Patent 5,707,559) duplicate of Ref. S

Reference Y (U.S. Patent 5,578,253) discloses alkyl-stabilized dioxetanes which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference Z (U.S. Patent 6,036,892) discloses spiroadamantyl-stabilized dioxetanes having water-solubilizing groups which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference AA (U.S. Patent 6,218,135) discloses cycloalkyl-stabilized dioxetanes which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference BB (U.S. Patent 6,228,653) discloses cycloalkyl-stabilized dioxetanes which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference CC (U.S. Patent 5,603,868) discloses cycloalkyl-stabilized dioxetanes which can be triggered to produce

chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference DD (U.S. Patent 6,107,036) discloses heterocyclic stabilized dioxetanes which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference EE (U.S. Patent 4,952,707) discloses cycloalkyl-stabilized dioxetanes which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference FF (U.S. Patent 6,140,495) discloses cycloalkyl-stabilized dioxetanes which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference GG (U.S. Patent 6,355,441) discloses heterocyclic stabilized dioxetanes which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference HH (U.S. Patent 6,461,876) discloses cycloalkenyl-stabilized dioxetanes which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds are useful in assays, including enzyme-linked assays.

Reference II (U.S. Patent 5,770,743) discloses spiroadamantyl-stabilized dioxetanes having labeling groups for attachment to biomolecules and which can be triggered to produce chemiluminescence by cleaving a protecting group. The compounds

are useful in assays, including enzyme-linked assays.

Reference JJ (U.S. Patent 4,935,342) describes a method of purifying cellular or viral nucleic acids from a biological sample by binding nucleic acids to an anion exchange column material at a lower salt molarity than the molarity at which the target nucleic acids elute therefrom, washing said column with an aqueous salt solution of a second chloride molarity, and eluting the bound nucleic acids with a salt solution having a higher chloride molarity.

Reference KK (U.S. Patent 4,997,932) also describes a method of purifying nucleic acids from a biological sample by binding nucleic acids to an anion exchange column material and eluting sequentially with a low salt molarity solution and then with an high salt molarity solution.

Reference LL (U.S. Patent 5,057,426) describes a method for separating long-chain nucleic acids from other substances by fixing long-chain nucleic acids onto a porous anion exchanger matrix having a particle size of from about 15 to about 250 μm and a pore diameter of about 100 to 2500 nm, washing the porous matrix to separate the other substances from the long-chain nucleic acids, and removing the fixed long-chain nucleic acids from the porous matrix.

Reference MM (U.S. Patent 5,075,730) describes a process for purifying DNA from a liquid mixture by combining the liquid mixture with a chaotropic agent and contacting the resulting combination mixture with silica in the form of diatomaceous earth

to selectively adsorb DNA, washing the silica with a buffer containing from about 20% to about 95% of a lower alkyl alcohol to remove non-adsorbed matter, and eluting said DNA from said silica with water or a low salt buffer.

Reference NN (U.S. Patent 5,155,018) describes a process for isolating biologically active RNA from a biological source by contacting said the source with particulate siliceous material in the presence of an acidified, concentrated chaotropic salt solution, to bind RNA to said particles, removing said particle-bound RNA from said source, and separating said biologically active RNA from said particles.

Reference OO (U.S. Patent 5,234,809) describes a process for isolating nucleic acid from a starting material by mixing the starting material, a chaotropic substance and a nucleic acid binding solid phase, separating the solid phase with the nucleic acid bound thereto from the liquid, and washing the solid phase nucleic acid complexes.

Reference PP (U.S. Patent 5,599,667) describes a method for purifying a polynucleotide greater than 100 nucleotides in a sample from shorter oligonucleotides 10 to 100 nucleotides long by contacting the sample with a solid support comprising a plurality of cations selected from ammonium, immonium and guanidinium ions, to bind the polynucleotide but not the shorter oligonucleotides, wherein the polynucleotide is at least three times longer than the shorter oligonucleotides, and separating the oligonucleotides from the support-bound polynucleotide.

Reference QQ (U.S. 5,665,582) claims a method for reversibly anchoring a biological material to a solid support having a reversible polymer placed thereon, attaching a reversible linker to the polymer, linking the biological material to the linker with a binding composition, and then subsequently releasing the biological material. The binding composition is defined as a separate substance, i.e. a complementary nucleic acid, an antibody or a binding protein, which is dispersed in or coated on the reversible polymer.

Reference RR (U.S. Patent 5,948,624) describes a method for isolating targets, including nucleic acids, from a mixture by reacting targets with a conjugate having a detector portion linked by a photocleavable portion to a coupling portion. Targets are chemically coupled to the conjugate, separated, and then photochemically cleaved. The methods differ from the present invention in requiring covalent attachment of target nucleic acids to small molecule cleavable conjugates.

Reference SS (U.S. Patent 6,027,945) describes a method for isolating a biological target material from other material in a medium by combining silica magnetic particles and the medium, binding the target material to the particles, removing the complex from the medium with an external magnetic field, and separating the biological target material from the complex by eluting the biological target material.

Reference TT (U.S. Patent 6,060,246) discloses a method for isolating or detecting in a sample a polynucleotide analyte having

a target base sequence by using a rapid pairing reagent comprising a solid substrate linked to a capture component and a target-specific probe. The capture component non-selectively binds to polynucleotide molecules, while the target-specific probe selectively binds the target base sequence of the polynucleotide analyte.The rapid pairing reagent-polynucleotide analyte complex is exposed to conditions which release the polynucleotide molecules from the capture component without disrupting said substrate-probe-target complex. The capture component can be an amine having a pKa of about 4-8 which binds polynucleotides at a pH below its pKa and releases them at a pH substantially above its pKa. The capture component can be linked to the substrate via a cleavable linkage.

Reference UU (U.S. Patent 6,270,970) describes a mixed-bed solid phase and uses for isolating a target nucleic acid from a mixture. The solid phase comprises a first ion-exchanger solid phase which can bind to the target nucleic acid at a first pH, and release target nucleic acid at a second pH differing by at least 0.5 pH units; and a second ion-exchanger solid phase which can bind to the target nucleic acid at the second pH and release at the first pH; and both the first and second ion-exchangers having a capacity to release the bound target nucleic acid in the presence of an elution buffer.

Reference VV (U.S. Patent 6,447,764) describes a method for isolating anionic organic substances such as nucleic acids from aqueous systems by reversibly binding the organic substances to

non-crosslinked polymer nanoparticles in cationic, protonated form, forming charged polymer nanoparticles, separating the charged polymer nanoparticles from the aqueous system, and releasing the organic substance from the nanoparticles by raising the pH to deprotonate the positively charged groups.

Reference WW (U.S. Patent 6,780,327) describes a positively charged porous membrane for separating negatively charged molecules from a solution. The positive charge can be supplied by a pendant quaternary ammonium group. No cleavable linkers are disclosed.

Reference XX (U.S. Patent 6,914,137) describes a solid phase for reversibly binding nucleic acids in a sample, the product comprising a plurality of immobilized positively ionizable groups which bind nucleic acid at a first pH at which the ionizable groups are positively charged and release the nucleic acid at a second, higher, pH at which the charge on the ionizable groups is negative, neutral or less positive.

Reference YY (U.S. Patent Appl. Pub. 2003/0158333A1) discloses water-soluble polymeric agents bearing a terminal thioester reactive group for covalent coupling to cysteine or histidine residues of proteins. These polymeric solubilizing agents contain an internal cleavable disulfide linkage for later removal of the polymer from the protein.

Reference ZZ (U.S. Patent Appl. Ser. No. 10/715,284) filed concurrently with the filing of the subject application and shares a common disclosure.

Reference AB (Advanced Chem Tech 2003 catalog, pp. 105-150) provides a listing of commercially available polymeric resins used in solid supported peptide synthesis.

Reference AC (I. HUGHES, Tetrahedron Lett., (1996), 37, pp.7595-7598) discloses polymer-bound triphenylphosphonium salts as traceless supports in solid phase synthesis. In all applications the phosphonium salt group remains affixed to the polymeric solid phase.

Reference AD (P.TUNDO,et al., J. Am. Chem. Soc. (1982), 104, 6551-6555) discloses phase transfer catalysts immobilized on alumina and silica gel having a quaternary ammonium or phosphonium group.

Respectfully submitted,

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Richard S. Handley, Ph.D.
Registration No. 38,484

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	10/714,763
Filing Date	November 17, 2003
First Named Inventor	Hashem Akhavan-Tafti
Art Unit	1637
Examiner Name	S. Mummert
Attorney Docket Number	Lumigen 4.1-87

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A	US- 4699717	10-13-1987	Riesner	
	B	US- 5057426	10-15-1991	Henco	
	C	US- 4395271	07-26-1983	Beall	
	D	US- 4233169	11-11-1980	Beall	
	E	US- 4297337	10-26-1981	Mansfield	
	F	US- 4554088	11-19-1985	Whitehead	
	G	US- 5356713	10-18-1994	Charmot	
	H	US- 5395688	03-07-1995	Wang	
	I	US- 4774265	09-27-1988	Ugelstad	
	J	US- 5091206	02-25-1992	Wang	
	K	US- 5866099	02-02-1999	Owen	
	L	US- 6291166	09-18-2001	Gerdes	
	M	US- 4628037	12-09-1986	Chagnon	
	N	US- 4627040	06-09-1987	Josephson	
	O	US- 4695393	09-22-1987	Whitehead	
	P	US- 4698302	10-06-1987	Whitehead	
	Q	US- 4654267	03-31-1987	Ugelstad	
	R	US- 5411730	05-02-1995	Kirpotin	
	S	US- 5707559	01-13-1987	Schaap	

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	T	EP 0496822 B1	10-17-1990	Macherey		
	U	EP 1243649 A1	03-23-2001	Muller		
	V	EP 01036082	05-29-2002	Baker		
	W	03/053934 PCT Publication	07-03-2003	Akhavan-Tafti		

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	X	US- 5707559	01-13-1998	Schaap	
	Y	US- 5578253	11-26-1996	Schaap	
	Z	US- 6036892	03-14-2000	Arghavani	
	AA	US- 6218135	04-17-2001	Matsumoto	
	BB	US- 6228653	05-08-2001	Matsumoto	
	CC	US- 5603868	02-18-1997	Wang	
	DD	US- 6107036	08-22-2000	Heindl	
	EE	US- 4952707	08-28-1990	Edwards	
	FF	US- 6140495	10-13-2000	Bronstein	
	GG	US- 6355441	03-12-2002	Edwards	
	HH	US- 6461876	08-21-2000	Brij	
	II	US- 5770743	06-23-1998	Schaap	
	JJ	US- 4935342	06-19-1990	Seligson	
	KK	US- 4997932	03-05-1991	Reardon	
	LL	US- 5057426	10-15-1991	Henco	
	MM	US- 5075730	12-24-1991	Little	
	NN	US- 5155018	10-13-1992	Gillespie	
	OO	US- 5234809	08-10-1993	Boom	
	PP	US- 5599667	02-04-1997	Arnold	

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	QQ	US- 5665582	09-09-1997	Kausch	
	RR	US- 5948624	09-07-1999	Rothschild	
	SS	US- 6027945	02-22-2000	Smith	
	TT	US- 6060246	05-09-2000	Summerton	
	UU	US- 6270970	08-07-2001	Smith	
	VV	US- 6447764	09-10-2002	Degussa	
	WW	US- 6780327	07-05-2005	Baker	
	XX	US- 6914137	05-29-2002	Baker	
	YY	US- 2003/015833 A1	08-21-2003	Roberts	
	ZZ	US- 10/715,284	11/17/2003	Akhavan-Tafti	
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NON PATENT LITERATURE DOCUMENTS

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	AB	Advanced Chem. Tech. 2003, Catalog, pp. 105-150	
	AC	I. Hughes, Tetrahedron Letters, 1996, 37, pp. 7595-7598	
	AD	P. Tundo, et al., J. Am. Chem. Soc. 1982, 104, pp. 6551-6555	

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